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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,906	03/16/2004	Anthony J. Melkent	5074A-000010/DVB	3395
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EXAMINER				
COLELLO, ERIN L				
ART UNIT		PAPER NUMBER		
3734				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/801,906

Applicant(s)

MELKENT ET AL.

Examiner

ERIN COLELLO

Art Unit

3734

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-17, 19, 39-45 and 47-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-17, 19, 39-45 and 47-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/808)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of applicant's amendment filed May 12, 2008. Claims 2, 18 and 46 have been canceled without prejudice. Claims 1, 3-17, 19, 39-45, 47 and new claims 48-52 are pending and an action on the merits is as follows.

Applicant's arguments with respect to claims 1, 18, 19 and 39 have been considered but are moot in view of the new ground of rejection.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3-17, 19, 39-45, 47 and 48-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Funda et al. (5,572,999)** in view of **Foley et al. (US 6,226,548 B1)**.

Regarding claims 1, 4, 12, 14, 15, 39, 47, 48, 49, Funda discloses an apparatus for the placement of surgical implements, comprising: a first fixture having a first configuration and a second fixture different from the first fixture and having a second configuration (Figure 4, (240a), (240b)); a plurality of cannulas coupled to a fixture (Figure 4, (241a), (241b)) and independently adjustable relative to the fixture (Column 7, Lines 15-19; Column 13, Lines 17-28); wherein at least one of the plurality of cannulas

can be interchanged with a cannula having at least one of a different inner diameter or outer diameter (Column 7, Lines 9-25; wherein the manipulator can carry surgical instruments including a telescope or forceps which have different diameters); at least one trackable marker associated with the plurality of cannulas to enable an instrument location system to detect a position of each of the plurality of cannulas throughout a surgical procedure in real-time (Figure 3, (276); Figure 8a, (701); Column 6, Lines 14-20; Column 9, Lines 1-7 and 56-64; Column 10, Lines 1-9; Column 14, Lines 5-10); and a plurality of surgical implement receivers provided on the fixture for receiving surgical implements, at least one of the plurality of receivers being a flange substantially coaxially aligned with a respective one of the plurality of cannulas (Figure 4 see below; wherein the flange is the implement receiver and includes the cannula) ; a surgical navigation system that tracks the plurality of trackable markers to determine a position of each of the plurality of cannulas relative to an anatomy ; and a display that displays an icon representative of the position of each of the plurality of cannulas superimposed onto an image of the anatomy (Figure 1, (243), (247); Column 8, Lines 62-65; Column 9, Lines 16-20; Column 14, Lines 5-20).

Funda fails to explicitly disclose that the trackable markers are mounted on a frame that is coupled to a fixture.

However, Foley teaches that it is well known when using a computer-assisted surgical navigation system to have a variety of trackable markers mounted not only on the instruments but on the frame of the devices in order to have reference points that

can be tracked in the system (Column 3, Lines 15-28 and 61-67; Column 4, Lines 1-9; Column 8, Lines 54-67; Column 10, Lines 63-57).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of Funda to include markers placed on the frame, since such a modification enhances the device by providing reference points that can be used to track the system.

Funda as modified by Foley discloses all of the claimed limitations above but fails to explicitly disclose that different types of trackable markers can be used.

It would have been obvious to one of ordinary skill in the art to use different markers on different locations, since such a modification enhances the device by distinguishing the different portions of the device from each other.

Furthermore, it would also be obvious to use different fixtures that have different marker. Having different markers would allow the surgeon to visualize different areas in a different manner, such as with the use of an ultrasound or an MRI.

Funda as modified by Foley fails to explicitly disclose that at least one of the plurality of cannulas is individually adjustable to vary at least one of its inner diameter or outer diameter.

However, it would be obvious to have a cannula that can vary in diameter in order to allow different size instruments to enter the lumen.

Regarding claims 3, 10 and 11, Funda discloses a peripheral structure, coupled to the fixture, for maneuvering the plurality of cannulas during a surgical procedure to place the surgical implements; wherein the peripheral structure can be machine

operated or wherein the peripheral structure is capable of being a handle when the movement of the device is manually controlled by the surgeon (Figure 1, (242); Column 4, Lines 46-48).

Regarding claims 5, 6, 41, 42 and 43, Funda discloses that at least one of the plurality of cannulas is individually adjustable to vary its length and its angular positions (Column 4, Lines 40-45 and 66-67).

Regarding claims 7 and 8, Funda discloses that at least one angular position is an azimuth angular position measured in a horizontal reference plane associated with the fixture and at least one angular position is an elevation angular position measured in a vertical reference plane associated with the fixture (Figure 4, (241a), (241b)).

Regarding claims 9 and 51, Funda discloses that the fixture is interchangeable insofar as it is configured to accommodate at least one of: a variable number of cannulas, cannulas having a plurality of relative placements, or cannulas having a plurality of fixed relative angles (Column 4, Lines 40-45 and 66-67).

Regarding claims 13 and 45, Funda discloses that the surgical implement is at least one of a surgical tool or an implant (Figure 4, (241a, 241b); Column 7, Lines 10-24).

Regarding claim 16, Funda discloses that at least one of the plurality of cannulas includes a surgical instrument such as forceps which contains a serrated structure for gripping portions of a patient's anatomy (Column 13, Lines 17-28).

Regarding claims 17 and 44, Funda discloses that at least one trackable marker is an optical marker; wherein the mark is visible (Figure 3, (276); Figure 8a, (701); Column 6, Lines 14-20; Column 9, Lines 1-7 and 56-64; Column 10, Lines 1-9).

Regarding claims 19, Funda discloses all of the claimed limitations above but fails to explicitly disclose that the frame is removably coupled relative to the plurality of cannulas fixture using a dove-tail connection.

However, Foley teaches that it is well known when using a computer-assisted surgical navigation system to have a removably coupled frame relative to the fixture using a dove-tail connection (Figures 4D-F, (55), (56))

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the frame of Funda to include a removably couple frame as taught by Foley, since such a modification enhances the device by allowing the portions of the system to be removable in order to be sterilized.

Regarding claim 40, Funda discloses that the plurality of cannulas are positioned parallel to one another in the first configuration (Column 4, Lines 40-45 and 66-67; wherein the configuration of multiple articulating arms allows for the devices to be placed in any desired orientation including where the cannulas are positioned parallel).

Regarding claim 50, Funda discloses an imaging device operable to acquire one or more images of the anatomy (Column 8, Lines 62-65; Column 9, Lines 16-20; Column 14, Lines 5-20).

Regarding claim 52, Funda discloses a display that displays an icon representative of the position of each of the plurality of cannulas overlaid onto an image of the anatomy (Figure 1, (247); Column 8, Lines 62-65; Column 9, Lines 16-20; Column 14, Lines 5-20).

Response to Arguments

Applicant's arguments with respect to claims 1, 18, 19 and 39 have been considered but are moot in view of the new ground of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

1. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIN COLELLO whose telephone number is (571)270-3212. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Erin Colello/
Examiner, Art Unit 3734

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773